DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

g2663d

NOV 5 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronald K. Labrum
Group President, Allegiance Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

Dear Mr. Labrum:

This letter follows a review by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) of the labeling and promotional material regarding the Allegiance Healthcare Corporation's (Allegiance) Protegrity surgical glove. The review included information on your web site, (www.allegiancehealthcare.com) for the Protegrity surgical glove, information in the Protegrity glove pamphlet, and the information submitted to FDA by Allegiance for premarket notification [redacted] The Protegrity surgical glove was cleared as a coated powder free surgical latex glove with protein claims as surgical gloves with latex properties. This product is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our review revealed that both your web site and the pamphlet, Protegrity, eliminates the word "latex" from the proprietary name. The labeling cleared under [redacted] states that "the surgical glove was manufactured in accordance with the [redacted] Glove-compounded primarily from natural rubber latex with a latex caution statement on the labeling." The elimination of the word "latex" in the proprietary name could pose a health risk to the end users and patients allergic to latex.

Your Protegrity surgical glove, as currently labeled and promoted, is adulterated under section 501(f)(1)(B) of the Act, in that it is a class III device under section 513(f) and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

Your device is misbranded under section 502(o) of the Act in that a notice or other information respecting the new intended use of the device, as currently labeled and promoted, was not provided to the FDA as required by section 510(k) and 21 CFR 807.81(a)(3)(ii).

You should take prompt action to correct these deviations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

If you have questions or need additional assistance contact Carol Shirk of the General Surgery Devices Branch at 301-594-4595 or FAX 301-594-4636.

Sincerely yours,

Betty W. Collins for

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices
and Radiological Health